

SECTION 8B: PUMPS & DRUG ADMINISTRATION	POLICY: 8B.40
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PURPOSE:

- To provide instruction on the safe and proper administration of Entyvio (Vedolizumab).

POLICY:

- Entyvio will be administered by a trained registered nurse in accordance with a physician's order, any available / provided pharmacy or manufacturer instructions, and Agency policy.

GENERAL INFORMATION:

- Entyvio helps address inflammation in gastrointestinal tissue. It is used for the treatment of moderate to severe Ulcerative Colitis and moderate to severe Crohn's disease.
- The most common side effects of Entyvio include the common cold, headache, joint pain, nausea, fever, infections of the nose and throat, tiredness, cough, bronchitis, flu, back pain, rash, itching, sinus infection, throat pain, and pain in the extremities.
 - If a patient reports experiencing these symptoms after an infusion, they should be advised to report the symptoms to their physician for medical advice.

SPECIAL CONSIDERATIONS:

- If a patient reports having any symptoms of infection such as fever, chills, muscle aches, cough, blood in phlegm, shortness of breath, runny nose, sore throat, red or painful skin or sores on their body, excessive tiredness, diarrhea, stomach pain, weight loss, or pain during urination, the attending nurse shall notify the Agency so that notification to Pharmacy and MD can be coordinated.
- A registered nurse shall remain with the patient for the entirety of the infusion.
- Infusions are initiated at Week 0, Week 2 (two weeks from Week 0), and Week 6 (four weeks from Week 2). Maintenance dosing continues every 8 weeks thereafter (unless otherwise noted in the order).
- Entyvio is administered as a 300mg dose over 30 minutes via intravenous infusion (unless otherwise ordered). DO NOT administer as an IV push or bolus.

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- Entyvio should allowed to equilibrate to room temperature prior to infusion.
 - Entyvio should be stored at 2° to 8°C (36° to 46°F). If there are any doubts about the storage and viability of the drug, reach out to the Agency immediately so that confirmation may be sought from the Pharmacy.
- RN shall monitor for infusion-related reactions and hypersensitivity reactions including anaphylaxis, dyspnea, bronchospasm, urticaria, flushing, rash, and increased blood pressure and heart rate.
 - If anaphylaxis or other serious infusion-related reactions occurs, discontinue administration of Entyvio immediately and initiate appropriate treatment to include administration of anaphylactic medications as necessary and activating EMS.
 - Notify the Agency as soon as possible so that the Pharmacy & MD may be notified.

PROCEDURE:

1. Obtain and verify physician's orders including pre-medication orders, concentration, rate of infusion, and emergency protocols (in-date anaphylactic kit on-hand). If you notice any discrepancies in the orders, contact the Agency before proceeding.
2. Explain procedure and purpose to patient/caregiver.
3. Perform initial [Hand Hygiene](#) and maintain throughout the procedure.
4. Assemble supplies on a clean, dry surface. Ensure all supplies needed to complete the infusion from beginning to end are available. If any supplies are missing, notify the Agency immediately and prior to starting the infusion process.
5. Assess and record patient's vital signs to establish a baseline and ensure vital signs are not contraindicative to starting the infusion.
6. Establish IV access or assure access is in working condition. DO NOT tamper with medication until patent IV access is established and flushed. After 2 unsuccessful IV attempts, notify Agency immediately for further instruction on how to proceed.
7. Remove the flip off cap from the single dose vial and wipe the top of the vial with alcohol.
8. Reconstitute the lyophilized power in the vial with 4.8ml of sterile water. Insert the needle through the center of the stopper and direct the stream toward the glass wall of the vial to eliminate excessive foaming.

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9. Gently swirl the vial for ~15 seconds to dissolve the powder. DO NOT vigorously shake the vial. Allow the solution to sit for up to 20 minutes to allow for full reconstitution. If not fully dissolved, wait another 10 minutes.
10. Visually inspect the vial for particulate matter and/or discoloration prior to dilution. The solution should be clear or opalescent, colorless to light brownish-yellow, and free of particulates.
 - If the solution appears to have particulate matter or is discolored, DO NOT use it.
 - Reach out to the Agency immediately so that the Pharmacy can be notified.
 - Pharmacy will advise as to how to handle the medication (i.e. disposal, return shipping, etc.).
11. Check the expiration dates on each vial to ensure they are within date.
12. Prior to redrawing the reconstituted solution, gently invert the vial 3 times.
13. Immediately withdraw 5ml of solution from the vial.
14. The reconstituted solution is now ready for dilution. Add the 5ml of solution to a 250ml bag of 0.9% Sodium Chloride. Gentle mix the solution. DO NOT shake the bag.
15. Begin the infusion. Administer Entyvio intravenously over 30 minutes (unless another length of time is noted in the order). In most cases, Entyvio will be administered via gravity tubing unless the Pharmacy has provided a peristaltic pump.
16. Obtain another set of vital signs 15 minutes into the infusion and at infusion end. Your documentation should include at least 3 sets of vital signs: Baseline, 15 minutes after infusion start, and infusion end.
17. Once infusion is complete, flush the IV with 10ml of saline (unless a different amount is noted in the MD order).
18. Disconnect the patient and remove the IV.
19. Place a pressure dressing at the IV site.
20. Clean up your workspace and properly discard all waste ensuring that all needles have been placed in a sharps container.
21. Document the procedure, the patient's response to the procedure, and all lot numbers and expirations dates for vials used.

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22. **Note:** If the infusion is not completed, notify the Agency immediately so the Pharmacy can be notified, and advisement received on how to store or dispose of the medication properly.

- Examples for incomplete infusions include losing IV access that is unable to be re-established, symptoms of intolerance, medication is unusable or compromised (broken / leaking vial or discolored or altered in normal appearance). **NEVER** discard of the medication without speaking to the Agency first.